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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,421	11/21/2003	John Eric Peckham	03-0388 (US01)	3394
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EXAMINER				
CHENG, JACQUELINE				
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3768				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,421

Applicant(s)

PECKHAM, JOHN ERIC

Examiner

JACQUELINE CHENG

Art Unit

3768

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-19, 21-27, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-19, 21-27, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 2, 2010 has been entered.

Response to Arguments

2. Applicant's arguments filed June 2, 2010, with respect to the claim objections have been fully considered and are persuasive. The objections of claims 17, 18, and 21-23 have been withdrawn.

3. Applicant's arguments filed June 2, 2010 with respect to the rejection of claim 36 under 35 U.S.C. 112, first paragraph, and have been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicant that any three of the segments making up the closed shape comprise a marker wire having a first and second end offset from each other circumferentially AND ALONG the length of the device. Of the segments making up the closed shape 20 (fig. 9), segments 30 and 26 (see fig. 3a) have a first and second end offset from each other circumferentially about the longitudinal axis of the device but these first and second ends are *not also* offset from each other along the length of the device. The opposite is true for segments 28 and 24 which have first and second ends offset from each other along the length of

the device but are *not also* offset from each other circumferentially about the longitudinal axis of the device. The only segment that fulfills these two limitations of a first end offset from each other circumferentially about a longitudinal axis AND along the length of the device is either one of element 36a or 36b. If one of these elements is used to fulfill the marker wire of the claim, fig. 9 no longer also has a first and second directional indicator each comprising a portion of a symbol that connect to form a symbol. Since neither fig. 9, nor any of the other drawings, nor the specification, discloses three pieces that fulfills all of the limitations as claimed, the 3 U.S.C. 112, first paragraph rejection still stands.

4. Applicant's arguments with respect to the 35 U.S.C. 103(a) rejection over Makower '875 (US 6,302,875 B1) have also been fully considered but they are not persuasive. The examiner respectfully disagrees with the applicants arguments that the examiner asserts that Makower '875 discloses that the two symbols connects ONLY when taking an image from an angle to the longitudinal axis of the device. This was just one example of wherein the markers would connect to form a combined symbol. As the examiner stated in the previous office action when viewed from a proper rotational orientation (such as an orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis) the first indicator of the "O" element 126 in fig. 6b connects with the second indicator of the "R" element 200 in fig. 6b combining or "connecting" to form a symbol "O R" as can be seen in fig. 6b. The applicant has not claimed that the symbols parts must physically connect in the image. Therefore the previous rejection in view of Makower '875 still stands and is repeated below. In anticipation of claim amendments wherein the symbol parts physically connect in the image a rejection further in view of Ryan (US 6,576,009 B2) is added below.

5. In regards to the applicant's arguments of claim 21 as being obvious over Makower'875 in view of Makower'311 (US 6,579,311) the examiner holds that, for the same reasons as discussed above that the symbol of "O R" "connects" the examiner believes that the image of a solid circle concentrically aligned with an open circle of fig. 3d of Makower'311 "connects" to form a symbol. Also in particular, as to the applicants arguments that the lines of the markers of Fig. 3a and 3b of Makower'311 may be slightly misaligned, but would still appear as a single, solid line, and the use of simple lines are not a "symbol" the examiner would like to point out that the lines of the markers of the applicant's invention may also be slightly misaligned, but would still appear as a single solid line (eg. in aligning part 24 and 28 of fig. 1) as well as the applicant themselves create a "symbol" using simple lines (elements 36a, 36b of fig. 9 are "simple lines").
6. It is for these reasons it is believed that the previous rejection dated March 4, 2010 still stands and is repeated below along with a new rejection further in view of Ryan for the independent claims.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose an embodiment which has the marker wire having a first and a second end offset from each other in a circumferential direction and along the length of the medical device in combination with the first and second directional indicators that connect in an image to form a symbol when viewed in the proper rotation.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. ***Claims 1, 15, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875 (US 6,302,875 B1) further in view of Ryan (US 6,576,009 B2). Makower'875 teaches markers that can be used in conjunction with any passageway-forming catheters such as catheters, catheter sheaths, and balloon catheters with lumens and ports (abstract, col. 25 line 46-67). The passive marker has two portions (first portion and third portion) extending in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device which forms a continuous closed circuit (fig. 6b element 124) as well as a first directional indicator (fig. 6b element 200) and a second directional indicator (fig. 6b element 126) offset from the first directional indicator which forms a symbol of a target and R when viewed at a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis (the symbol is viewable over***

a rotational range of 5 degrees) to help in determining a rotational orientation of the device. The catheter is inserted into a bodily lumen and maneuvered to a desired location and then using the marker symbols, is rotated to the desired rotational orientation (col. 1 line 25-col. 2 line 20, col. 15 line 8-18). Makower'875 discloses that the markers of fig. 6b be made from radiopaque materials so it would be obvious to use any well known radiopaque material such as a metal wire as previously disclosed in Makower'875 (col. 16 line 23-24). Mokower'875 does not teach the first and second directional indicators physically connecting in the image. In the same field of endeavor of rotational markers for medical devices, Ryan discloses a rotational orientation marker including first and second directional indicators 162 and 164 (fig. 8a, 8b) which physically connect in an image when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device (see fig. 8b). It would be obvious to make the directional indicators in Makower'875 to physically connect in an image such as disclosed by Ryan for the purpose of providing precise angular alignment of the medical device (col. 12 line 38-41 of Ryan).

11. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875 in view of Makower'311 (US 6,579,311 B1) in view of Ryan. Makower'875 discloses using marker symbols to determine proper rotational orientation of a device. One of such embodiments (fig. 6a) has a marker in the shape of the letter R (element 200), and then two directional indicators (elements 122a and 122b) which when viewed from a proper orientation connect to form a symbol of "- -". Makower'311 discloses the same type of rotational orientation marker devices and that any other designs may be used so long as it provides for proper orientation of the device

(col. 10 line 50-59). So therefore it would be obvious to use instead of the letter R to use a letter G which would have a first end and a second end offset from each other in a circumferential direction and along the length of the device. Furthermore Makower'875 discloses that the markers can be made from radiopaque materials so it would be obvious to use any well known radiopaque material such as a metal wire as previously disclosed in Makower'875 (col. 16 line 23-24).). Makower'875 does not teach the first and second directional indicators physically connecting in the image. In the same field of endeavor of rotational markers for medical devices, Ryan discloses a rotational orientation marker including first and second directional indicators 162 and 164 (fig. 8a, 8b) which physically connect in an image when viewed from a proper rotational orientation about the longitudinal axis when viewed orthogonally to the longitudinal axis using an imaging device (see fig. 8b). It would be obvious to make the directional indicators in Makower'875 to physically connect in an image such as disclosed by Ryan for the purpose of providing precise angular alignment of the medical device (col. 12 line 38-41 of Ryan).

12. **Claims 1-7, 12, 15, 18, 19, 23-25, and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875 (US 6,302,875 B1). Makower'875 teaches markers that can be used in conjunction with any passageway-forming catheters such as catheters, catheter sheaths, and balloon catheters with lumens and ports (abstract, col. 25 line 46-67). The passive marker has two portions (first portion and third portion) extending in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device which forms a continuous closed circuit (fig. 6b element 124) as well as a first directional indicator (fig. 6b element 200) and a second directional indicator (fig. 6b

element 126) offset from the first directional indicator which forms a symbol of a target and R when viewed at a proper rotational orientation (the symbol is viewable over a rotational range of 5 degrees) to help in determining a rotational orientation of the device. The catheter is inserted into a bodily lumen and maneuvered to a desired location and then using the marker symbols, is rotated to the desired rotational orientation (col. 1 line 25-col. 2 line 20, col. 15 line 8-18). Makower'875 discloses that the markers of fig. 6b be made from radiopaque materials so it would be obvious to use any well known radiopaque material such as a metal wire as previously disclosed in Makower'875 (col. 16 line 23-24).

13. **Claims 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875 in view of Nash (US 2002/0032432 A1). Makower'875 discloses most of what is claimed except for the symbol being an arrow. It would be obvious to use any type of rotational indicator such as an arrow instead of the "R" as disclosed by Makower'875 as the style of rotational indicator is a design choice and using an arrow as a rotational indicator is well known in the art such as disclosed by Nash. Nash discloses using an arrow symbol as a rotational indicator (fig. 1 element 38, paragraph 0036).

14. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875 in view of Makower'311 (US 6,579,311 B1). Makower'875 discloses most of what is claimed as disclosed above except for the first and second directional indicator forming an arrow symbol. Makower'311 discloses the same type of rotational orientation marker devices wherein only three different embodiments as shown, however any other geometrical designs may be provided such that when visualization of a particular geometry occurs, it may be said that a proper orientation of the device has been achieved, or even non-geometrical markers can be used as long

as it provides proper orientation of the device (col. 10 line 50-59). Therefore it would be obvious to use a well known geometric shapes such as angular lines which forms a particular geometry of an arrow. Furthermore the shape of the marker device is a design choice as both provide the same function of determining proper rotational orientation of a device.

15. **Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'875 in view of Makower'311. Makower'875 discloses using marker symbols to determine proper rotational orientation of a device. One of such embodiments (fig. 6a) has a marker in the shape of the letter R (element 200), and then two directional indicators (elements 122a and 122b) which when viewed from a proper orientation connect to form a symbol of "- -". Makower'311 discloses the same type of rotational orientation marker devices and that any other designs may be used so long as it provides for proper orientation of the device (col. 10 line 50-59). So therefore it would be obvious to use instead of the letter R to use a letter G which would have a first end and a second end offset from each other in a circumferential direction and along the length of the device. Furthermore Makower'875 discloses that the markers can be made from radiopaque materials so it would be obvious to use any well known radiopaque material such as a metal wire as previously disclosed in Makower'875 (col. 16 line 23-24).

16. **Claims 1-6, 13, 24, 25 and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'311 further in view of Makower'875. Makower'311 teaches a catheter comprising a lumen and a port with a passive marker that has two portions (first portion and third portion) extending in a circumferential direction and two portions (second portion and fourth portion)

extending in a direction parallel to the longitudinal axis of the medical device to form a continuous closed circuit (fig. 3c, 3d). The catheter is inserted into a bodily lumen and maneuvered to a desired location. Once placed in a desired location the device is rotated until the operator sees that the marker is aligned properly (col. 10 line 1-22). The passive marker device can be created using any known set of materials which would allow for radiographic, fluoroscopic, magnetic, sonographic, or electromagnetic detection of the position and orientation of the device (col. 9 line 6-10) so it would be obvious to use any well known material such as disclosed by Makower'875. Makower'875 discloses using wire to form an imagable marker (col. 16 line 23-24). Makower'875 further teaches besides just a marker in a circular shape, the marker has two directional indicators which connect to form a symbol when rotated in the proper orientation. It would be obvious to add the two directional indicators such as the "O" (element 126, fig. 6b) and the "R" (element 200, fig. 6b) of Makower'875 to Makower'311 for the purpose of making sure that the medical device is properly rotationally orientated, in particular to be certain that the device isn't rotated 180° from the desired orientation.

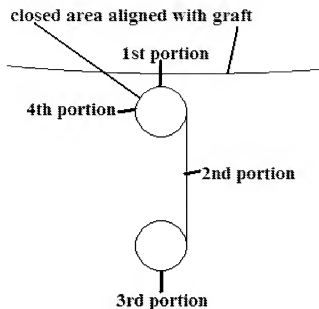
17. **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower'311 in view of Makower'875 further in view of Plaia (US 6,497,711 B1). Makower'311 discloses that the catheter device is used as an access port through which a procedure may be performed such as ablating a volume of tissue. It would be obvious to use any well known device with the catheter device of Makower'311 depending on the procedure desired to be performed such as using a rotating ablation device as disclosed by Plaia (abstract) if an ablation of tissue was desired to be performed.

18. **Claims 1-6 and 24-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (US 6,660,024 B1) in view of Makower'875. Flaherty discloses a medical device such as a catheter having a lumen and port that has a marker for determining rotational orientation of the device. The marker comprises two portions (first portion and third portion) extending in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device which forms a continuous closed circuit (fig. 3f). The marker surrounds an imaging transducer which is positioned closely adjacent to an exit port rendering the marker extending about a rim of the port. Furthermore in another embodiment the exit port is located directly at the point at which the transducer is affixed rendering the marker extending around and surrounding the rim of the port (col. 9 line 19-60). Flaherty does not explicitly disclose what the marker is made of. It would be obvious to use any well known radiopaque marker well known in the art such as wire as disclosed by Makower'875 (col. 16 line 23-24). Flaherty also does not disclose two directional indicators connecting together to form a symbol. Makower'875 discloses having two directional indicators such as an "O" and a "R" which connect to form a symbol ("O R"). It would be obvious to add two directional indicators to the marker of Flaherty for the purpose of making sure that the port is aligned properly and is not flipped 180° from the proper rotational orientation.

19. **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty in view of Makower'875 further in view of Plaia (US 6,497,711 B1). Flaherty discloses a marker extending around and surrounding the rim of an exit port of which any instrument such as a tissue penetrator can be used for exiting out of the exit port. It would be obvious to use any well known device with the device of Flaherty depending on the procedure desired to be performed

such as ablating a volume (penetrating tissue) using a rotating ablation device as disclosed by Plaia (abstract)

20. **Claims 1-5, 8-11, and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lombardi (US 5,824,042) in view of Makower'875. Lombardi discloses a marker attached to a medical device such as a stent or a stent-graft which is self-expandable (col. 1 line 6-7, col. 14 line 44-45). The marker extends such that two portions (first portion and third portion) extends in a circumferential direction and two portions (second portion and fourth portion) extending in a direction parallel to the longitudinal axis of the medical device forming a continuous closed circuit (fig. 10a, 10b, and fig below). Furthermore the top of the graft is aligned with the closed area defined by the marker wire. Lombardi does not teach a first and second directional indicators offset from one another wherein image of the first and second directional indicators connect to form a symbol. Makower'875 discloses a first (fig. 6b element 126) and second (fig. 6b element 200) directional indicators offset from one another which connect to form a symbol ("O R"). It would be obvious to add the two directional indicators of Makower'875 to Lombardi for the purpose of making sure that the graft is properly rotationally aligned and is not flipped 180° from the proper rotational orientation.



21. **Claims 15, 19, and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong (US 2002/0099431 A1) in view of Makower'875. Armstrong discloses a stent which is covered by a partial graft wherein the stent graft is aligned with a radiopaque marker. Armstrong does not explicitly disclose what type of radiopaque marker is used. It would be obvious to use any radiopaque marker such as disclosed in Makower'875 as discussed above.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE CHENG whose telephone number is (571)272-5596. The examiner can normally be reached on M-F 10:00-6:30.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline Cheng/
Examiner, Art Unit 3768